UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Jacqueline Clay, individually and on behalf of all others similarly situated, *Plaintiff*, vs. The Procter & Gamble Company, *Defendant.*	Case No. 1:21-cv-11133-JPC-GWG JURY TRIAL DEMANDED

Plaintiff's Memorandum of Law in Opposition to Defendant's Motion to Dismiss

Table of Contents

Table of Authorities

Cases

Statutes

Regulations

Defendant's motion lacks merit. It should be denied.

I. The FDC Act does not preempt Ms. Clay's claims.

The FDC Act preempts a state deceptive advertising claim in only two situations. If claims challenge a purportedly deceptive statement on a food, drug, or cosmetics label that the FDA has specifically found to be truthful, they are preempted. Or, if claims seek an affirmative warning or disclosure that the FDA has specifically found is not required, they are preempted too.

Here, Ms. Clay challenges Defendant's labels for falsely stating that DayQuil is "Non-Drowsy" even though it causes drowsiness. The FDA has never evaluated this statement, much less found it to be truthful. And Ms. Clay's claims would not require any affirmative warning; they would simply require removing "Non-Drowsy." Her claims, therefore, are not preempted.

A. The FDC Act does not generally preempt state deceptive advertising laws.

The FDC Act has an express preemption clause. That clause preempts state laws that would impose requirements "different from," "in addition to," or "not identical" to ones the Act imposes. 21 U.S.C. § 379r(a).

The Act broadly prohibits food, drug, and cosmetics labels that are "false or misleading in any particular." 21 U.S.C. § 343(a) (food), § 352(a) (drugs), § 362(a) (cosmetics). State deceptive advertising laws prohibit the same thing: false and misleading labels. *E.g., Ault v. J.M. Smucker Co.*, 2014 U.S. Dist. LEXIS 67118 (2014 WL 1998234), at *15 (S.D.N.Y. May 15, 2014). So in general, what deceptive advertising laws require is "identical" to (not "different from" or "in addition to") what the Act requires.[1] The Act, therefore, generally does not preempt deceptive advertising laws.

Instead, the Act only preempts specific types of deceptive advertising claims: ones asserted

[1] *In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Practices Litig.*, 701 F. Supp. 2d 356, 370 (E.D.N.Y. 2010) (cleaned up) ("the FDA has traditionally regarded state law as a complementary form of drug regulation that provided an additional, and important, layer of consumer protection that complements FDA regulation."); *Jovel v. I-Health, Inc.*, 2013 U.S. Dist. LEXIS 139661 (2013 WL 5437065), at *15 (E.D.N.Y. Sep. 27, 2013) (generally, "consumer protection claims founded on [] falsity are not preempted"); *Moreno v. Vi-Jon, Inc.*, , 2021 U.S. Dist. LEXIS 40032 (2021 WL 807683), at *30 (S.D. Cal. Mar. 3, 2021) ("Generally, courts have found that claims based on parallel state laws that mirror the relevant sections of the FDCA are not preempted").

against labeling that the FDA has reviewed, approved, and found to be truthful (and not "false or misleading in any particular."). This is because Congress tasked the FDA with interpreting and implementing the Act, so its interpretations are generally binding. *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 844 (1984). So if the FDA concludes that labeling is truthful (and not "false or misleading"), that conclusion is binding. State claims seeking to prohibit such labeling would impose a requirement "different from" the Act and so are preempted.

B. Challenges to labeling that FDA regulations expressly approve are preempted; ones to labeling that FDA regulations do not address are not.

For new prescription drugs, the FDA generally reviews and approves the entire label. *Dolin v. GlaxoSmithKline LLC,* 901 F.3d 803, 806 (7th Cir. 2018); 21 U.S.C. § 355(b)(1)(A). So statements on the label of such drugs have generally been reviewed, approved, and found to be truthful and not misleading. *Id.* The FDC Act therefore broadly preempts state law claims challenging them.

But for certain over-the-counter drugs like DayQuil, the story is different. The FDA does not individually review or approve the label, or the statements on it. Instead, the FDA issues regulations, called "monographs." Complying with monographs allow manufacturers to "bypass" individual review. *Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312, 319 (S.D.N.Y. 2017).

Monographs list the active ingredients that are approved for use for certain types of over-the-counter drugs (for example, cough medicines). *E.g.*, 21 C.F.R. § 341.1 (approved ingredients for cough medicines). Monographs also set forth the statements that must be included on the label, and ones that can optionally be included on the label. *E.g.*, 21 C.F.R. § 341.74 (labeling for cough medicines); *see* 21 C.F.R. § 201.66(c) (over-the-counter labels must include monograph information).

Monographs do not, however, attempt to address every conceivable marketing claim and say whether it is prohibited or allowed, truthful or deceptive. *See generally* 21 C.F.R. §§ 341 *et. seq.* Rather than attempting this impossible feat, the FDA has simply required that, in addition to complying with the specific requirements set forth in the monograph, over-the-counter drug labels must also

comply with the general requirements of the Act. 21 § C.F.R 330.1 (in addition to complying with the monograph, drug must be "labeled in compliance with chapter V" of the Act). This includes the general prohibition on labeling that is "false or misleading in any particular." 21 U.S.C. § 352 (Chapter V of the Act).

Thus, the FDA does not specifically address most over-the-counter drug labeling, and instead generally requires it to be truthful and not misleading. Nor does it individually review over-the-counter drug labels to make sure that they comply with this truthfulness requirement. So, most over-the-counter drug labeling has not been specifically evaluated or expressly approved by the FDA. And as result, the Act does not preempt most challenges to over-the-counter drug labeling. *See, e.g.*, *Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312, 318-23 (S.D.N.Y. 2017) (monograph governing toothpaste does not preempt claims challenging statements about the whitening effects of toothpaste, because the monograph did not address the challenged statements). Instead, it only preempts challenges to over-the-counter drug labeling in very specific circumstances.

First, if an FDA regulation such as a monograph requires or expressly allows a particular statement to be included on a drug label, then challenges to that statement are preempted. *See, e.g., Patellos v. Hello Prods., LLC*, 523 F. Supp. 3d 523, 529-530 (S.D.N.Y. 2021) (challenges to claims about the efficacy of fluoride preempted by monograph approving fluoride as effective); *Mills v. Warner-Lambert Co.*, 581 F. Supp. 2d 772, 790 (E.D. Tex. 2008) (challenge to claims that drug was effective against lice preempted by monograph approving drug as effective for the treatment of lice).

Courts have also found preemption where the FDA has addressed and expressly allowed the substance, though not the exact phrasing, of a challenged statement. For example, in *Bowling*, a monograph expressly allowed toothpaste labels to state that toothpaste "prevent[s] tooth decay" and to "explain how decay is prevented." *Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312, 322 (S.D.N.Y. 2017) (explaining *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 373 (S.D.N.Y. 2014)).

The court concluded that this preempted a challenge to a claim that toothpaste "restores enamel." Because the claim explained how tooth decay is prevented, the FDA had expressly allowed the "substance" of the claim. *Id* at 323.

And finally, courts have found preemption where state law claims sought to add an affirmative warning or disclosure to a label, when applicable FDA regulations did not require it. *See Critcher v. L'Oreal USA, Inc.*, 959 F.3d 31, 36-37 (2d Cir. 2020) (claims seeking additional disclosures about the quantity of face cream that could be dispensed from Defendant's products were preempted by FDA regulations requiring only the "net quantity" in the bottle to be disclosed); *Harris v. Topco Assocs., LLC*, 2021 U.S. Dist. LEXIS 89716 (2021 WL 1885981), at *8 (N.D. Ill. May 11, 2021) (plaintiff sought to require affirmative disclosure); *Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271, 1282 (C.D. Cal. 2008) (same). The rationale here is that when the FDA issues comprehensive regulations identifying all of the disclosures that must be placed on a product's label, it necessarily concludes that no other disclosure is required. Said differently, by issuing a list of all the required disclosures and omitting a particular disclosure from the list, the FDA is affirmatively approving the sale of products without that disclosure. Therefore, if a state law claim seeks to require that disclosure, it is attempting to impose a requirement "in addition to" those of the Act.

When, however, FDA regulations merely address the same subject matter as a statement, but do not approve either its letter or its spirit, this does not preempt challenges to that statement. For example, in *Geffner v. Coca-Cola Co.*, the plaintiff challenged Diet Coke for having a misleading name. 343 F. Supp. 3d 246, 252 (S.D.N.Y. 2018). The FDA had issued regulations addressing this precise subject matter—the use of the word "Diet" in the name of soft drinks. But those regulations did not "affirmatively approve or require" the term, and instead "merely exempt[ed] soft drinks using

the term 'diet' from certain labeling requirements." *Id.* Accordingly, there was no preemption. *Id.* [2] Regulations addressing the subject matter generally do not tell us that the FDA actually reviewed and approved a particular challenged statement. Moreover, as described further below, under controlling law, the scope of preemption must be construed narrowly and any doubt or ambiguity must be resolved against preemption. *See infra* at p. 8.

As demonstrated next, Ms. Clay's claims fall into the non-preempted category. They challenge the DayQuil label for affirmatively making a false and misleading "Non-Drowsy" statement, not for omitting a warning or disclosure. And the challenged "Non-Drowsy" statement has never been approved by the FDA (much less clearly and unambiguously).

C. Ms. Clay's claims would simply require Defendant to remove the deceptive "Non-Drowsy" label, not to add a "drowsiness warning."

Defendant repeatedly asserts that Ms. Clay's claims are preempted because she seeks to require a "drowsiness warning" to be added to the DayQuil label. Mot. 5, 9, 10, 12-14. But this misstates the Complaint and attacks a straw man.

Ms. Clay's claims do not seek—nor would they require—an affirmative disclosure or "drowsiness warning" to be added. She challenges the DayQuil label because it prominently displays the affirmative misrepresentation "Non-Drowsy"—not because it fails to disclose drowsiness as a side effect or lacks a "drowsiness warning." [3] In fact, the Complaint alleges that if Defendant had

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[2] *Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312, 322 (S.D.N.Y. 2017) (FDA decision to not regulate peroxide-containing products as teeth-whiteners did not preempt challenge to representations about the whitening effect of such products, because although it addressed teeth whitening, it did not "address the substance of" the challenged claims, and instead merely addressed the same subject matter); *Bell v. Publix Super Mkts.*, Inc., 982 F.3d 468, 483-85 (7th Cir. 2020) (FDA regulations allowing products containing non-cheese ingredients to be called "grated cheese" did not preempt state law claims challenging a "100% grated cheese" label, because the regulations did not approve the 100% modifier).

[3] *See, e.g.*, Complaint at 6 ("Defendant's Non-Drowsy representations are misleading to reasonable consumers"); *id.* 2-5 (identifying the affirmative "Non-Drowsy" representation as the challenged aspect of the label, and setting forth examples); *id.* 9 (identifying that "[t]he package said 'Non-Drowsy' prominently on the label" as the misrepresentation Ms. Clay relied on); *id.* 10 (identifying "Whether Defendant's labeling of the Non-Drowsy DayQuil Products as 'Non-Drowsy' is deceptive and misleading" as an issue common to each class member); *id.* 13-18 (identifying the affirmative "Non-Drowsy" representation as the basis for liability in each asserted claim).

"simply omitted the false and misleading statement, 'Non-Drowsy,' from its products," the label would have been lawful. Complaint ¶24; *see id.* ¶23 (Mucinex, a product with DXM, is lawful even though it does not have a warning, because it is not labeled "Non-Drowsy"). Thus, far from seeking a drowsiness warning, the Complaint disavows such a requirement.

After alleging that the affirmative "Non-Drowsy" representation is what renders the label deceptive, the Complaint alleges that the accused products "do not disclose anywhere on their packaging that they do or can cause drowsiness, or that drowsiness is a side effect." Complaint ¶13. The point here is not that a disclosure is required regardless of any affirmative misrepresentation. It is that there is nothing on the label that qualifies the "Non-Drowsy" misrepresentation to make it non-deceptive. *Cf. Sitt v. Nature's Bounty, Inc.*, 2016 U.S. Dist. LEXIS 131564 (2016 WL 5372794), at *42 (E.D.N.Y. Sep. 26, 2016) (warning disclaimer can sometimes cure otherwise deceptive label). Remove the affirmative misrepresentation (as Ms. Clay seeks), and everyone agrees that no warning is required.

Thus, Ms. Clay's claims would not impose labeling requirements "on top of" those imposed by the Act. *Cf.* Mot. 10. They would simply forbid Defendant from voluntarily adding deceptive content to its labels—which is something the Act's general prohibition of "false or misleading" labeling already forbids. When, as here, Ms. Clay's claims "ultimately require[]" DayQuil "to remove these allegedly misleading advertising statements from its product labels, such a result does not run afoul of the FDCA." *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 758 (9th Cir. 2015); *Bell v. Publix Super Mkts., Inc.*, 982 F.3d 468, 485 (7th Cir. 2020) ("The FDCA's preemption provision means that, while states may not require sellers to add further labeling that is not required by federal law, they may prevent sellers from voluntarily adding deceptive content that is not required by federal law"); *Ault v. J.M. Smucker Co.*, 2014 U.S. Dist. LEXIS 67118 (2014 WL 1998234), at *9 (S.D.N.Y. May 15, 2014) (challenge to "all natural" label on bioengineered foods not preempted)

D. FDA regulations do not affirmatively allow DayQuil to be marketed as "Non-Drowsy"—much less clearly and unambiguously.

The FDA has never affirmatively allowed DayQuil to be marketed as "Non-Drowsy"—in the monograph governing DayQuil or anywhere else.

As Defendant concedes, the monograph does not require, or expressly allow, products containing DXM to be labeled "Non-Drowsy." *See* 21 C.F.R. § 341.74. Nor does it approve the "substance" of this claim. *Cf. Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312, 318-23 (S.D.N.Y. 2017). It does not say, for example, that products containing DXM can be labeled "non-sedative," that manufacturers can represent that they "won't make you sleepy," or anything like this.

The monograph does, however, address and expressly allow other statements. 21 C.F.R. § 341.74(b)(3) (setting forth several optional statements that "the labeling of the product may contain"). For example, saying that DayQuil "[t]emporarily helps you cough less" is expressly permitted. *Id.* If the FDA intended to allow products containing DXM to be labeled "Non-Drowsy," it would have included "Non-Drowsy" in the list of approved statements. That the FDA did not do so demonstrates that the FDA did *not* intend to approve "Non-Drowsy."

Defendant argues that FDA regulations implicitly allow products containing DXM to be marketed as "Non-Drowsy" for two reasons. We address each in turn.

Defense Argument 1: FDA regulations do not specifically prohibit "Non-Drowsy."

Defendant argues that because the FDA monograph on cough medicines does not specifically "prohibit the labeling of products containing dextromethorphan as 'non-drowsy,'" it implicitly allows such labeling. Mot. 9, 11. As explained above, however, FDA monographs do not identify and specifically prohibit every conceivable deceptive statement. Instead, they only identify statements that are required or approved. And they expressly provide that any other statement (ones not specifically addressed) must comply with the Act's general prohibition on false or misleading labeling (something the FDA itself does not police for all over-the-counter labeling

statements). *See* 21 § C.F.R 330.1(c). Thus, that the monograph governing DayQuil does not specifically address "Non-Drowsy" does not tell us that the FDA reviewed this statement and concluded that it is truthful. It tells us that the FDA has *not* reviewed it.

Moreover, "[i]n fields traditionally occupied by the states, such as health and safety regulation, there is a strong presumption against federal preemption." *Jovel v. I-Health, Inc.*, 2013 U.S. Dist. LEXIS 139661 (2013 WL 5437065), at *13 (E.D.N.Y. Sep. 27, 2013). "Where Congress enacts an express preemption clause, that presumption requires courts to read the clause narrowly." *Id* at 12. "For a court to conclude that Congress has preempted a state [deceptive advertising claim], its intent to do so, must be 'clear and manifest.'" *Moreno*, 2021 U.S. Dist. LEXIS 40032 (2021 WL 807683), at *30. "Courts have a duty to accept the reading [of a preemption clause] that disfavors pre-emption when such a reading is plausible." *Geffner v. Coca-Cola Co.*, 343 F. Supp. 3d 246, 251-52 (S.D.N.Y. 2018) (cleaned up); *Becerra v. Dr Pepper/Seven Up, Inc.*, 2018 U.S. Dist. LEXIS 54937 (2018 WL 1569697), at *8-9 (N.D. Cal. Mar. 30, 2018). Accordingly, courts must take a narrow view when determining whether the FDC Act requirements (as implemented by FDA regulations) are not "identical to" state law claims. Unless it is "clear and manifest" that the FDA approved a particular challenged statement (as opposed to merely addressing the same subject matter), there is no preemption. What's more, in determining whether regulations demonstrate the requisite "clear and manifest" intent, the Court must view all facts "in the light most favorable to" Ms. Clay and draw all inferences in her favor. *Galper v. JP Morgan Chase Bank, N.A.*, 802 F.3d 437, 443-44 (2d Cir. 2015).

The mere fact that the FDA has not specifically prohibited a claim falls far short of a "clear and manifest intent" that would be needed to conclude that the FDA has affirmatively allowed that claim to be made. For this reason, courts have repeatedly rejected the argument that a statement is allowed merely because it is not specifically prohibited. For example, in *Bell*, plaintiffs claimed that it was deceptive to use the label "100% grated parmesan cheese" on products containing non-cheese

ingredients. *Bell v. Publix Super Mkts., Inc.*, 982 F.3d 468, 483 (7th Cir. 2020). FDA regulations allowed products to be labeled "grated cheese" even though they included non-cheese ingredients, and did not specifically prohibit the "100%" modifier. "From this silence, [the defendants] argue[d] that any state-law ruling that prohibited them from using the phrase '100% cheese' would establish a requirement not identical to those set out in the FDA's" regulations and was therefore preempted. *Id.* The Seventh Circuit rejected this everything-not-specifically-forbidden-is-allowed argument. Plaintiffs "seek only to stop defendants from voluntarily adding deceptive language to the federally permitted labels …. Absent contrary language in [an FDA regulation] that protects a particular statement, [the FDC Act] does not expressly preempt state-law prohibitions on deceptive statements that sellers add voluntarily to their labels or advertising." *Id* at 484.

Similarly in *Astiana*, the plaintiff claimed that it was deceptive to use the label "all natural" on cosmetics containing chemicals. *Astiana*, 783 F.3d 753 at 758. The defendant argued that "the FDA has never issued regulations regarding the use of 'natural' on cosmetics labels" and that "the FDA's failure to issue specific regulations on the subject is tantamount to a conscious decision by the agency to permit any use of this term a manufacturer sees fit." *Id.* The Ninth Circuit flatly rejected this argument. "By [defendant]'s logic, a manufacturer could make any claim—wild, untruthful, or otherwise—about a product whose contents are not addressed by a specific regulation. The [FDC Act], however, proscribes statements that are 'false or misleading in any particular,' not statements that are 'prohibited by specific FDA regulations.'" *Id.* 758; *see Hawkins v. Kroger Co.*, 906 F.3d 763, 771-72 (9th Cir. 2018) ("Because the FDA regulations do not authorize the contested statement, Hawkins's labeling claims are not preempted.").

As a third example in *Canale*, the plaintiff claimed that certain teeth-whitening claims on toothpaste were deceptive. The defendant argued the claims were preempted because the FDA's monograph governing toothpaste did not specifically prohibit them. *Canale v. Colgate-Palmolive Co.*,

258 F. Supp. 3d 312, 318-23 (S.D.N.Y. 2017). The court rejected this argument. Because the monograph did not expressly approve the statements, the defendant had "not identified any federal requirements applicable to its Optic White products beyond the FDCA's general prohibition against false and misleading labeling." *Id.* And "[b]ecause that general prohibition is identical to the requirement Plaintiff seeks to impose through her claims under state law, those claims are not expressly preempted." *Id.*; *Ault*, 2014 U.S. Dist. LEXIS 67118 (2014 WL 1998234), at *9 (challenge to "all natural" claim not preempted even if it was not specifically prohibited).

Citing *Critcher,* Defendant asserts that "the FDCA's general prohibition on 'false or misleading' statements cannot be used to circumvent preemption." Mot. 10 (citing *Critcher v. L'Oreal USA, Inc.*, 959 F.3d 31, 36 (2d Cir. 2020)). Defendant suggests that *Critcher* holds that state law claims challenging an affirmative misrepresentation are preempted unless FDA regulations expressly prohibit it. But *Critcher* did not, as Defendant suggests, break with decades of precedent holding otherwise. In fact, the plaintiffs in *Critcher* were not challenging an affirmative statement at all. They alleged that the labels were misleading because they "*omitted* certain critical information." *Id.* (emphasis added). Moreover, the supposedly missing "critical information" had to do with how much cream could be dispensed from the defendant's products. And the FDA had issued detailed regulations requiring only the net quantity of product (and not the dispensable quantity) to be disclosed. So the claims sought "an additional disclosure on [cosmetics] packaging" that the FDA specifically decided not to require. *Id.* This is why they were preempted. *See* §I(B) above. [4]

Defendant also cites *Bowling.* There, the district court found the monograph preempted a challenge to a claim that toothpaste "restores enamel." According to Defendant, the court reached this conclusion because FDA regulations "did not affirmatively prohibit the phrase." Mot. 13 (cleaned up) (quoting *Bowling*). But as later decisions in this district interpreting *Bowling* confirm, this

[4] *Bimont v. Unilever U.S., Inc.*, 2015 U.S. Dist. LEXIS 119908 (2015 WL 5256988), at *20-22 (S.D.N.Y. Sep. 9, 2015), also cited by Defendant, dealt with this same issue but for deodorants instead of face creams.

is not what *Bowling* turned on. Although the monograph in *Bowling* did not permit the "restores enamel" claim specifically, it permitted toothpaste labels "(1) to represent that [products containing certain ingredients] prevent tooth decay and (2) to provide further labeling to explain how decay is prevented." *Canale v. Colgate-Palmolive Co.*, 258 F. Supp. 3d 312, 322-23 (S.D.N.Y. 2017) (explaining *Bowling*). And the *Bowling* court concluded that "restores enamel" explained how tooth decay is prevented. *Id.* "Thus, while the FDA may not have considered the exact language addressed in *Bowling*, it had clearly addressed the substance of the claims at issue" and had affirmatively allowed the substance of the challenged claims. *Id.* It was for this reason—not because the regulations did not expressly prohibit the precise "restores enamel" phrasing—that the state law claims were preempted. "If the quoted language in *Bowling* were taken literally and out of context, a manufacturer could [make misleading claims about its toothpaste's ability to clear acne], and then point to the Anticaries Monograph [which does not specifically prohibit such an assertion] to immunize it against state law claims challenging that assertion. Congress cannot have intended such sweeping preemption." *Id.* at 323. [5]

Accordingly, here, Ms. Clay's claims are not preempted merely because the cough medicine monograph does not forbid the "Non-Drowsy" claim. Defendant's contrary argument would immunize broad swaths of misleading claims that the FDA never approved. "Where the FDA is unable to address a potentially deceptive practice, state claims are one of the few means of safeguarding consumers and therefore should not be preempted by the FDA's inaction." *Ault v. J.M. Smucker Co.*, 2014 U.S. Dist. LEXIS 67118, at *10 (S.D.N.Y. May 15, 2014).

Defense Argument 2: Because FDA regulations do not require a drowsiness warning, they allow DayQuil to be marketed as "Non-Drowsy."

[5] Similarly, in *In re PepsiCo, Inc., Bottled Water Mktg.& Sales Pracs. Litig.,* 588 F. Supp. 2d 527, 538 (S.D.N.Y. 2008), the plaintiffs asserted that nature graphics on bottled water misleadingly suggested "spring" water. But the FDA had expressly considered this kind of representation (nature graphics suggestive of spring water) and concluded that, so long as the water was purified, this was not materially misleading to consumers. So the FDA had expressly considered the specific labeling that was being challenged, and concluded it was not misleading.

Defendant argues that by not requiring a drowsiness warning on products containing DXM, the FDA has allowed such products to be affirmatively labelled "Non-Drowsy." Mot. 9-10, 12-13. This argument is contrary to controlling law and common sense. That the FDA does not require a drowsiness warning on the label of DXM does not even suggest that the FDA intended to allow it to be marketed as "Non-Drowsy." And it certainly does not demonstrate the "clear and manifest" intent that would be necessary to give it preemptive effect. *See supra p.* 8 (collecting cases).

To begin, consumer products in general, and over-the-counter drugs in particular, are not required to include a comprehensive disclosure of all material dangers and side effects on their label. Instead, regulators use their discretion in deciding which limited set of warnings it is crucial to warn the public about, based on the best information available at the time. For example, the Consumer Product Safety Commission requires products of certain dimensions to include a "CHOKING HAZARD" warning on their label if they are marketed to infants or toddlers. 16 C.F.R. § 1500.20. This is because objects of these dimensions are most likely to cause choking deaths. But it does not mean that the Commission determined that these are the *only* products that can cause choking. That inference would have absurd and dangerous consequences. For example, it would allow companies to market toys slightly larger than the threshold dimensions to infants and toddlers and affirmatively claim on the package: "NOT A CHOKING HAZARD." Permitting this false assertion would cause deaths. Over 1 in 7 nonfood choking deaths are caused by objects larger than the dimensions that trigger the warning requirement. Ex. A (*Characteristics of Objects that Cause Choking in Children,* JAMA 274:1763 at 1766, col. 1 (1995)). The Commission focused its warning on particular dimensions because those dimensions presented the gravest danger of choking, not because it determined that all other dimensions present no material danger.

This same logic applies to the "Non-Drowsy" claims. The FDA determined, that, unlike for certain other cough medicines, at the time the monograph issued in 1987 there was not enough data

demonstrating that DXM presented a sufficiently severe and frequent risk of drowsiness to warrant a mandatory label warning. But this does not tell us that the FDA concluded that DayQuil causes *no material drowsiness*, such that the "Non-Drowsy" label would be truthful. That question was not before the FDA. The only question before the FDA was whether an affirmative warning should be mandated. Moreover, the "Non-Drowsy" label is not something that the FDA would (or even could) allow, because it is false and misleading and therefore runs afoul of section 352 of the Act. If the FDA had concluded that products containing DXM can be labeled "Non-Drowsy," that conclusion would be arbitrary and capricious, and therefore not binding. *Chevron*, 467 U.S. at 844.

Defendant's logic would have absurd and dangerous implications. For example, the monograph governing DayQuil does not require a warning to avoid alcoholic beverages (this warning is required for other cough medications, 21 C.F.R. § 341.74). By Defendant's logic, we can infer from this that FDA has concluded that it is safe to consume alcohol while taking DXM, and that Defendant is permitted to market DayQuil as "safe to consume with alcohol." But such an inference is demonstrably wrong. Despite not mandating an alcohol warning on the label, the FDA warns consumers elsewhere to "[a]void alcohol if you are taking…cough-cold products with the ingredient dextromethorphan." [6] So the cough medicine monograph demonstrably does not require a label warning of all dangers known to the FDA. Moreover, as explained next, the reason the FDA warns consumers not to mix alcohol and DXM is that the FDA knows DXM causes drowsiness.

During the rulemaking process, the FDA recognized that cough suppressants such as DXM might trigger "a secondary pharmacological action … tantamount to a sedative effect" and that multiple references found drowsiness to be a side effect for DXM. 48 Fed. Reg. 48,576, 48,589 (Oct. 19, 1983). Despite this, the FDA ultimately concluded that it was "not aware of data demonstrating that … dextromethorphan … require[s] a drowsiness warning." *Id.* In other words,

[6] https://www.fda.gov/drugs/choosing-right-over-counter-medicine-otcs/over-counter-medicines-whats-right-you.

it concluded that the data at the time (in the late 1980's) was not enough to warrant a mandatory drowsiness warning, despite some evidence that DXM does cause drowsiness.

So, in short, the FDA concluded that DXM *does* cause drowsiness. The evidence decades ago was not enough to convince the FDA that the risk was so extreme that it required a label warning. But it confirms that an affirmative "Non-Drowsy" claim is false and misleading.

Moreover, since the 1980s, additional studies and data have come out showing that DXM causes drowsiness in over 10% of users. *See* Complaint ¶17 (collecting sources). This is why numerous reliable sources warn that DXM causes drowsiness. *Id.* It is also why regulators that have evaluated the issue more recently, such as the FAA, have taken affirmative steps to address this danger, such as prohibiting pilots who have taken DXM from flying. *See* Complaint ¶19. This recent evidence (not before the FDA at the time) further confirms that the affirmative "Non-Drowsy" claim at issue here is false and misleading. It also shows why the FDA's 1987 decision not to require an affirmative drowsiness warning—which was expressly based on lack of data and not on a conclusion that DXM does not cause drowsiness—does not give drug makers who now know better a license to falsely assert that their medicines are "Non-Drowsy" to boost their sales.

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In sum, the alleged facts and record evidence demonstrate that the FDA did *not* approve the "Non-Drowsy" claim. And viewing these facts in the light most favorable to Ms. Clay and drawing all reasonable inferences in Ms. Clay's favor, we certainly cannot say that the FDA had a "clear and manifest" intent to approve the "Non-Drowsy" claim. Thus, there cannot be preemption.

II. The Complaint sufficiently pleads that DayQuil labels are false and misleading.

A. The Complaint sufficiently pleads that DXM causes drowsiness.

The Complaint cites multiple sources showing that DXM causes drowsiness, including (1) peer-reviewed research showing that, at levels lower than in Dayquil, DXM causes drowsiness in

over 10% of users, *id.* ¶17; (2) the FDA's adverse event database showing that drowsiness is one of the most common side-effects, *id.* ¶18; and (3) FAA regulations prohibiting pilots from flying after taking DXM (and specifically DayQuil) because it causes drowsiness, *id.* ¶¶16-19.

Defendant objects that the cited research "was co-authored by a pharmaceutical company that produced levodropropizine," and "did not use a placebo group" and speculates that the drowsiness documented in the study "could be attributable to other causes." Mot. 16-17. These arguments go to the "weight that should be given to this study" and "cannot be resolved on a motion to dismiss." *Hughes v. Ester C Co.*, 930 F. Supp. 2d 439, 461-462 (E.D.N.Y. 2013); *see Quinn v. Walgreen Co.*, 958 F. Supp. 2d 533, 544 (S.D.N.Y. 2013) (same). [7]

Defendant cites *Excevarria* and *Kardovich*. But those cases involved a total "mismatch" between the allegations and the cited studies. *Kardovich v. Pfizer, Inc.*, 97 F. Supp. 3d 131, 138 (E.D.N.Y. 2015) (study addressed "wholly different health issues"); *Excevarria v. Dr Pepper Snapple Grp., Inc.*, 764 F. App'x 108, 110 (2d Cir. 2019) (plaintiff alleged that diet soda causes weight gain, but cited study found no "causal relationship" between the two). Here, in contrast, the cited study is directly on point. The Complaint alleges that DXM causes drowsiness, and the study found that "[s]omnolence [i.e. drowsiness[8]] is a common side effect of" DXM and that DXM causes more drowsiness than another antitussive drug. Complaint ¶17. So here, "[u]nlike . . . *Kardovich* . . . . there is no 'mismatch' between plaintiffs' theory of harm and the scientific materials relied on." *Krommenhock v. Post Foods, LLC*, 255 F. Supp. 3d 938, 963 (N.D. Cal. 2017).

Defendant asserts that the FAA banned DayQuil not because it contains DXM, but based on a mistaken belief that it contains an antihistamine. Mot. 18. This assertion again asserts disputed facts and draws unsupported inferences in Defendant's favor. Worse, it is false. The FAA banned

[7] Defendant also asserts that the FDA adverse event database is unverified and may contain duplicate reports. Mot. 17. This too injects purported facts beyond the pleadings and draws speculative inferences in Defendant's favor.

[8] Somnolence means drowsiness. Complaint ¶17, n.4 (Merriam Webster).

"Dayquil" specifically because it "contains dextromethorphan." Complaint ¶19.

B. The Complaint sufficiently pleads that DayQuil causes drowsiness.

Defendant argues that DayQuil "contains four active ingredients" and the Complaint does not "suggest[] that a product with the combination of these four ingredients causes drowsiness in consumers." Mot. 15. This argument has no merit.

DayQuil contains DXM and that DXM causes drowsiness. Complaint ¶16-19. On a motion to dismiss, this permits (actually compels) the inference that DayQuil causes drowsiness. Moreover, the FAA *specifically* prohibits pilots from flying after taking DayQuil because "DayQuil" contains DXM and causes drowsiness. *Id.* ¶19. And it was DayQuil that made Plaintiff drowsy. *Id.* ¶28.

Defendant contends that another DayQuil ingredient "can have a 'mild central nervous system stimulation' at certain doses." Mot. 15. Defendant asks the Court to infer that at the (unspecified) doses, this other ingredient might completely counteract the drowsiness effect of DXM. But this would draw inferences in favor of Defendant, based on facts outside the pleadings. And if DayQuil does not cause drowsiness, why does the FAA ban it for causing drowsiness?

Defendant's two out-of-circuit cases are inapposite. In *GNC*, the plaintiff claimed that the accused products were ineffective. *Toback v. GNC Holdings, Inc.*, 2013 U.S. Dist. LEXIS 131135 (2013 WL 5206103), at *16-17 (S.D. Fla. Sep. 13, 2013). To plausibly allege this, it was necessary to allege that *none* of the active ingredients caused the benefits. But the complaint only alleged that one (not all) ingredient was ineffective. *Id.* The situation here is not analogous: that one ingredient of several ingredients in a product causes drowsiness is all it takes for the product to cause drowsiness.

In *Eckler,* plaintiff alleged that Equate glucosamine was ineffective. *Eckler v. Wal-Mart Stores, Inc.*, 2012 U.S. Dist. LEXIS 157132 (2012 WL 5382218), at *4 (S.D. Cal. Oct. 31, 2012). But that plaintiff failed to allege a "critical point:" that the cited studies tested a comparable amount of glucosamine. *Id.* at *33, n.8. Here, "patients in [the] clinical study were given an even smaller

dosage of DXM (15 mg three times a day) than the recommended dose found in many DayQuil products." Complaint ¶17. If a smaller dose causes drowsiness, a larger dose does too (likely more).

III. Ms. Clay can bring class claims for absent class members that live in other states.

A. Ms. Clay has standing to assert non-New York claims.

Defendant asserts that Ms. Clay "lacks statutory standing to advance claims under non-New York consumer protection statutes." Mot. 19. What Defendant means is that Ms. Clay could not herself assert, say, a Washington claim, because she bought the product in New York. *Id.* at 20. But Ms. Clay is not asserting the non-New York claims on her own behalf; she is asserting them on behalf of class members who purchased products in other states. And this is allowed by controlling law.

Class actions "are an exception to the general rule that one person cannot litigate injuries on behalf of another." *Langan v. Johnson & Johnson Consumer Cos.*, 897 F.3d 88, 93 (2d Cir. 2018). So "long as the named plaintiffs have standing" to assert their home-state laws, "concern about whether it is proper for a class to include out-of-state, nonparty class members with claims subject to different state laws is a question of predominance" for class certification. *Id.* at 92-93.

Langan is on all fours with this case. There, a Connecticut resident alleged that the defendant falsely labeled its products as "natural." *Id.* at 91. The plaintiff proposed a multi-state consumer protection class. *Id.* Defendant argued that the plaintiff lacked standing to bring claims "governed by the laws of states other than Connecticut." *Id.* at 92. The Second Circuit rejected this argument. It held that a plaintiff "has standing to bring a class action on behalf of unnamed, yet-to-be-identified class members from other states under those states' consumer protection laws" so long as she has standing under her home state's statute. *Id.* Whether a plaintiff can bring class claims for people that live in other states is a "question of predominance," not of standing. *Id.* at 96. Courts therefore "defer consideration of [statutory standing] to the class certification stage," where they are

"better positioned to determine whether class members have standing to pursue claims under the relevant state laws, and whether the claims adequately satisfy the commonality and typicality requirements of Rule 23." *Morrow v. Ann Inc.*, 2017 U.S. Dist. LEXIS 9770, at *13 (S.D.N.Y. Jan. 24, 2017); *Kaatz v. Hyland's Inc.*, 2016 U.S. Dist. LEXIS 87348, at *10-11 (S.D.N.Y. July 5, 2016) (same).

Defendant argues that *Langan* dealt only with "*constitutional (Article III) standing* to bring a class-action claim on behalf of out-of-state consumers," and that it "has no bearing on this *statutory standing* question." Mot. 20. This misstates *Langan*, which addressed exactly the same issue that Defendant raises here. The parties in *Langan* agreed that the plaintiff had Article III standing (i.e. injury in fact). *Langan* at 92. "The only point of contention [was] whether Langan ha[d] standing to bring a class action on behalf of . . . class members from other states under those states' consumer protection laws." *Id.* In other words, while the Court did not use the term "statutory standing," the issue was precisely the same as in this case. [9] Namely, can a plaintiff assert claims under other states' consumer protection statutes on behalf of absent class members who live there? The Second Circuit held that this is a question of predominance for class certification, not a standing issue. *Id.* at 96.

After *Langan* (and also before *Langan*) the overwhelming weight of authority has held that plaintiffs may assert claims on behalf of putative class members from other states at this stage, and that deciding whether those claims can proceed under Rule 23 is an issue for class certification. [10]

Defendant relies on *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, plc*, 2018 U.S.

[9] The term "statutory standing" is "misleading and a misnomer" because it "in fact is not a standing issue, but simply a question of whether the particular plaintiff has a cause of action under the statute." *Am. Psychiatric Ass'n v. Anthem Health Plans, Inc.*, 821 F.3d 352, 359 (2d Cir. 2016) (internal quotations omitted).

[10] *See, e.g.*, *Morrow v. Ann Inc.*, 2017 U.S. Dist. LEXIS 9770, at *14 (S.D.N.Y. Jan. 24, 2017); *In re Dig. Music Antitrust Litig.*, 812 F. Supp. 2d 390, 406 (S.D.N.Y. 2011); *Blessing v. Sirius XM Radio Inc.*, 756 F. Supp. 2d 445, 452 (S.D.N.Y. 2010); *Reid v. GMC Skin Care USA Inc.*, 2016 U.S. Dist. LEXIS 14001 (2016 WL 403497), at *21 (N.D.N.Y. Jan. 15, 2016); *Daniel v. Tootsie Roll Indus., LLC*, 2018 U.S. Dist. LEXIS 129143 (2018 WL 3650015), at *13 (S.D.N.Y. Aug. 1, 2018); *Donnenfeld v. Petro, Inc.*, 333 F. Supp. 3d 208, 225 (E.D.N.Y. 2018); *Holve v. McCormick & Co., Inc.*, 334 F. Supp. 3d 535, 552 (W.D.N.Y. 2018); *Kaatz v. Hyland's Inc.*, 2016 U.S. Dist. LEXIS 87348, at *10-11 (S.D.N.Y. July 5, 2016); *In re Grand Theft Auto Video Game Consumer Litig.*, 2006 U.S. Dist. LEXIS 78064 (2006 WL 3039993), at *10 (S.D.N.Y. Oct. 25, 2006); *In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Practices Litig.*, 701 F. Supp. 2d 356, 377 (E.D.N.Y. 2010).

Dist. LEXIS 220574 (2018 WL 7197233) (S.D.N.Y. Dec. 26, 2018). But that case followed *Langan* and rejected defendants' standing challenge. *Id.* at *21. That court called the issue "Article III" standing, but it was the same issue that Defendant presents here. *Id.* at *57.[11]

The other New York court cases that Defendant cites are inapposite or contrary to *Langan*. In *Robainas v. Metro. Life Ins. Co.*, the court held that the named plaintiffs "[had] not demonstrated a sufficiently concrete injury" to establish Article III standing under the law of *any* state. 2015 U.S. Dist. LEXIS 138354, at *14 (2015 WL 5918200) (S.D.N.Y. Oct. 9, 2015). Here, it is undisputed that Ms. Clay has alleged an injury-in-fact under New York law (the same one alleged in *Langan*—that "she paid a premium . . . for the products," *Langan* at 92.) And in *In re HSBC Bank, USA, N.A.*, the court held that "plaintiffs lack standing to bring claims on behalf of a class under the laws of states where the named plaintiffs have never lived or reside." 1 F. Supp. 3d 34, 50 (E.D.N.Y. 2014). But the Second Circuit later rejected this approach in *Langan*. *Langan* at 88.

B. The Complaint sufficiently pleads the non-New York claims.

Defendant asserts that "Plaintiff has not even attempted to allege how P&G violated the non-New York consumer protection statutes. Instead, she simply lists the other statutes that were supposedly violated." Mot. 19. This is simply false. *See* Complaint ¶42-47. And what Plaintiff actually did do is indisputably sufficient to plead the non-New York claims.

For a multi-state consumer protection law claim, the complaint needs to "outline[] only the broad contours of the state law causes of action for states other than those in which they reside." *In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Practices Litig.*, 701 F. Supp. 2d 356, 378 (E.D.N.Y. 2010) (single sentence describing the shared elements of 43 state statutes was sufficient).

[11] The *Sergeants* court explained that *Langan* does not foreclose a 12(b)(6) challenge for other flaws (not standing) with consumer protection claims from other states. *Id.* at *61-63 (dismissing claims from states that do not permit indirect purchaser claims). But here Defendant attacks standing, and that attack is foreclosed by controlling law.

[12] Moreover, the need for a "high level of detail" for each state is further diminished where, like here, the claims are limited "to state laws that share substantive foundational features." *Sergeants*, 2018 U.S. Dist. LEXIS 220574, at *96.

Here, Count I includes a seven-state consumer protection class (which includes New York). These states have materially-similar consumer protection laws. Complaint ¶42; *see Allen v. ConAgra Foods, Inc.*, 331 F.R.D. 641, 666 (N.D. Cal. 2019) (certifying a group that includes these states). And the Complaint does not merely list the state laws—it alleges that the DayQuil products violate each shared element of each materially-similar law. Complaint ¶¶43-47. Given the similarity of the elements, this is sufficient to state a claim for each state. *See In re Bayer Corp*, 701 F. Supp. 2d at 378; *Sergeants,* 2018 U.S. Dist. LEXIS 220574, at *96.

In the cases cited by Defendant, the plaintiffs did not outline the elements of those statutes or make any attempt to connect them to defendants' conduct. *See In re Aluminum Warehousing Antitrust Litig.*, 833 F.3d 151, 163 (2d Cir. 2016) (complaint listed statutes "without pleading any of their elements"); *In re Trilegiant Corp.*, 11 F. Supp. 3d 82, 124 (D. Conn. 2014) (same); *McGarvey v. Penske Auto. Grp.*, 639 F. Supp. 2d 450, 465 (D.N.J. 2009) (same). Here, by contrast, the Complaint sets forth the elements of those statutes and applies them. *See Bayer*, 701 F. Supp. 2d at 378-79 ("[U]nlike the *McGarvey* plaintiffs, [the complaint does] more than merely listing state consumer fraud statutes. . . Plaintiffs have drawn the connection between the statutes and defendant's offending conduct.") (cleaned up); *MSP Recovery Claims, Series, LLC v. Sanofi Aventis United States LLC,* 2019 U.S. Dist. LEXIS 54086 (2019 WL 1418129), at *49 (D.N.J. Mar. 29, 2019) (same).

IV. The Complaint states a claim under the GBL.

A. The GBL's safe harbor does not apply.

[12] There the complaint alleged: "The acts, practices, misrepresentations and omissions by Defendant described above, and Defendant's dissemination of deceptive and misleading advertising and marketing materials in connection therewith, occurring in the course of conduct involving trade or commerce, constitute unfair methods of competition and unfair or deceptive acts or practices within the meaning of each of the above-enumerated statutes." *Id.*

The GBL safe harbor is an "affirmative defense" that requires Defendant to show that the "non-drowsy" representation fully complies with "federal requirements under the FDCA and its implementing regulations." *Bardsley v. Nonni's Foods LLC*, 2022 U.S. Dist. LEXIS 47104 (2022 WL 814034), at *32-33 (S.D.N.Y. Mar. 16, 2022). "GBL's safe harbor provisions have no effect if the claims are not preempted." *Bourbia v. S.C. Johnson & Son, Inc.*, 375 F. Supp. 3d 454, 465 (S.D.N.Y. 2019). Because Defendant's preemption defense fails, so does its safe harbor defense. *See* §I.

B. Plaintiff suffered a cognizable injury under the GBL.

A complaint pleads a sufficient injury under the GBL if it includes a "general allegation that [plaintiff] would not have paid a price premium but for the defendant's misrepresentations." *Rodriguez v. Hanesbrands Inc.*, 2018 U.S. Dist. LEXIS 28002, at *16 (E.D.N.Y. Feb. 20, 2018) (collecting cases).[13] Here, the Complaint alleges that Ms. Clay "overpaid for [DayQuil] because [it is] sold at a price premium due to Defendant's misrepresentations." Complaint ¶¶47, 54, 63. And the Complaint explains why this is so: consumers value and demand cough medicine that is truly "Non-Drowsy." *Id.* ¶27. This is sufficient to state an economic injury.

Defendant relies on *Izquierdo v. Mondelez Int'l, Inc.*, 2016 U.S. Dist. LEXIS 149795 (2016 WL 6459832), at *18 (S.D.N.Y. Oct. 26, 2016). But that court erred by requiring that a complaint include proof (and even quantification) of a price premium. Indeed, "at least three district courts in this Circuit have disagreed with the holding of *Izquierdo* because it 'contradicts the weight of the law in this Circuit.'" *Izquierdo v. Panera Bread Co.*, 450 F. Supp. 3d 453, 465 (S.D.N.Y. 2020) (collecting cases); *see Orlander v. Staples, Inc.*, 802 F.3d 289, 302 (2d Cir. 2015) (endorsing more general allegations of a price premium); *Rodriguez v. Hanesbrands Inc.*, No. 2018 U.S. Dist. LEXIS 28002, at *16 (E.D.N.Y. Feb. 20, 2018) (collecting cases); *Cooper v. Parsky*, 140 F.3d 433, 440 (2d Cir. 1998) (a

[13] *See, e.g., Fishon v. Peloton Interactive, Inc.*, 2020 U.S. Dist. LEXIS 208861 (2020 WL 6564755), at *30 (S.D.N.Y. Nov. 9, 2020); *Orlander v. Staples, Inc.*, 802 F.3d 289, 302 (2d Cir. 2015); *Kacocha v. Nestle Purina Petcare Co.*, 2016 U.S. Dist. LEXIS 107097, at *51 (S.D.N.Y. Aug. 11, 2016); *In re Scotts EZ Seed Litig.*, 304 F.R.D. 397, 409 (S.D.N.Y. 2015).

court does not "assay the weight of the evidence" for a motion to dismiss).

Defendant contends that Plaintiff could not have paid a price premium for DayQuil because Defendant's NyQuil product costs the same as DayQuil. Mot. 22 (citing pharmacy webpages). This argument fails. As the cited webpages indicate, NyQuil and DayQuil have a number of differences besides the presence/absence of the "Non-Drowsy" claim, including different active ingredients and indications. One important difference is that, as the name suggests, NyQuil is intended for *night-time* use, whereas DayQuil is formulated and intended for use during the day, when consumers do not want to feel drowsy. [14] So NyQuil is not "comparable" in the way that Defendant contends. Defendant is, once again, asserting its own facts and drawing unsupported inferences its way.

Defendant also asserts that the Complaint fails to plead injury under a full refund theory. Mot. 21. [15] This argument fails on two levels. To begin, Plaintiff indisputably pleaded that she paid a price premium, which establishes economic injury. This alone is sufficient. Moreover, one measure of GBL damages is "the consideration paid [for the product] minus the actual value." *Rodriguez v. It's Just Lunch Int'l*, 2018 U.S. Dist. LEXIS 131870 (2018 WL 3733944), at *13 (S.D.N.Y. Aug. 6, 2018). If a plaintiff received no value, she "may seek to recover the full [amount she] paid to defendant[] as damages," i.e., a "a "full refund." *Id* at 13-14*; see Dash v. Seagate Tech. (US) Holdings, Inc.*, 27 F. Supp. 3d 357, 361 (E.D.N.Y. 2014) (a full refund only foreclosed if consumer receives "something of value"). And whether Ms. Clay and the class received value from the DayQuil products turns on disputed facts that will have to be resolved by the trier of fact. "Plaintiff[] will succeed or fail on [her full refund] theory based on whether [she is] able to prove [DayQuil] is

[14] https://www.cvs.com/shop/vicks-nyquil-cold-flu-nighttime-relief-liquicaps-24-count-24-pack-prodid-1011902.

[15] In contrast, in *Small* (Mot. 21) cigarette purchasers failed to allege any injury other than that "deception itself." *Small v. Lorillard Tobacco Co.*, 720 N.E.2d 892, 894 (N.Y. 1999)*; see Fishon v. Peloton Interactive, Inc.*, 2020 U.S. Dist. LEXIS 208861 (2020 WL 6564755), at *31 (S.D.N.Y. Nov. 9, 2020) (distinguishing *Small).* Likewise, in *Baron,* plaintiffs "failed to allege actual harm or that [they] sustained a pecuniary injury." 840 N.Y.S.2d 445, 448 (App. Div. 3rd Dept. 2007).

worthless" at trial. *Rodriguez* at *14 (quotation marks omitted). This cannot be decided on the pleadings.

V. The Complaint states an express warranty claim.

Defendant's arguments are mostly duplicative of its GBL arguments. Mot. 22-23. For the reasons discussed above, these arguments all fail. Defendant also asserts that "Plaintiff failed to provide timely notice" of her warranty claim. Mot. 23. This is incorrect.

A "buyer must within a reasonable time after [s]he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." *Mogull v. Pete & Gerry's Organics, LLC*, 2022 U.S. Dist. LEXIS 35237 (2022 WL 602971), at *13 (S.D.N.Y. Feb. 28, 2022) (quoting N.Y. U.C.C. § 2-607(3)(a)). Ms. Clay pleads timely notice. She discovered Defendant's breach after buying DayQuil in "late 2021." Complaint ¶28. She sent pre-suit notice in December 2021. *Id.* ¶46.

Defendant asserts that this notice was untimely because it was sent "just six days before the Complaint was filed." Mot. 23. But the "question is not whether [Plaintiff] gave defendant enough notice before filing suit; it is whether they gave reasonably prompt notice 'after [she] discover[ed] or should have discovered' the alleged breach." *Tyman v. Pfizer, Inc.*, 2017 U.S. Dist. LEXIS 212879, at *58-59 (S.D.N.Y. Dec. 27, 2017); *see Mogull v. Pete & Gerry's Organics, LLC*, 2022 U.S. Dist. LEXIS 35237 (2022 WL 602971), at *13 (S.D.N.Y. Feb. 28, 2022).

Defendant contends that it must have "'a reasonable time' to cure any breach before Plaintiff file[s] suit." Mot. 23 (citing *Singleton v. Fifth Generation, Inc.*, 2016 U.S. Dist. LEXIS 14000 (2016 WL 406295), at *40 (N.D.N.Y. Jan. 12, 2016)). This misstates *Singleton*. That court explained that a plaintiff must provide notice within a reasonable time *of discovering* the alleged breach, to provide defendant a chance to mitigate damages. *Singleton* at *40-41. Ms. Clay has done that. [16]

VI. The Complaint states a Magnuson-Moss claim.

[16] The plaintiff in *Singleton* failed to provide pre-suit notice. *Id.* Defendant's other cited case, *Barton*, involved a failure to provide pre-suit notice. *Barton v. Pret A Manger (USA) Ltd.*, 535 F. Supp. 3d 225, 246 (S.D.N.Y. 2021).

The Magnuson-Moss Warranty Act "incorporates and federalizes state-law breach of warranty claims, including state-law standards for liability and damages." *Cosgrove v. Or. Chai, Inc.*, 520 F. Supp. 3d 562, 586 (S.D.N.Y. 2021) (quotation marks omitted). Thus, "breach of express warranty and MMWA claims stand or fall together." *Brady v. Basic Research, L.L.C.*, 101 F. Supp. 3d 217, 234 (E.D.N.Y. 2015). As discussed above, the Complaint pleads a breach of express warranty. No more is needed to state a Magnuson-Moss claim. *Id.*

Defendant asserts that its "Non-Drowsy" representation is "not a covered 'warranty' as defined in the MMWA." Mot. 24. But courts "in this Circuit have concluded that the 'MMWA . . . simply allows a consumer to recover damages under existing state law." *Newton v. Kraft Heinz Foods Co.*, 2018 U.S. Dist. LEXIS 241406 (2018 WL 11235517), at *28 n.6. (E.D.N.Y. Dec. 18, 2018). [17] Because Ms. Clay states a claim for breach of warranty, she states a Magnuson-Moss claim. Moreover, she states a claim even under Defendant's cramped interpretation: "Non-Drowsy" promises that the products will provide a specified performance (they will not make you drowsy) over a specified period of time (during the dosing interval on the label). *See* Complaint ¶76.

Defendant also asserts that "Plaintiff cannot satisfy the $25 amount-in-controversy threshold for MMWA claims." Mot. at 24. But the Class Action Fairness Act (CAFA) "provides an alternative basis for jurisdiction without regard for the MMWA." *Weisblum v. Prophase Labs, Inc.*, 88 F. Supp. 3d 283, 293 (S.D.N.Y. 2015); Complaint ¶7 (pleading CAFA jurisdiction).

Defendant relies on *Ebin*, which held that a court cannot assert CAFA jurisdiction over a Magnuson-Moss claim. *Ebin v. Kangadas Food Inc.*, 2013 U.S. Dist. LEXIS 107224 (2013 WL 3936193), at *4 (S.D.N.Y. July 25, 2013). But the "vast majority of courts have held that, where its

[17] *See Kaatz v. Hyland's Inc.*, 2016 U.S. Dist. LEXIS 87348, at *17 (S.D.N.Y. July 5, 2016) ("Although the MMWA is a federal statute, liability under it is based on state warranty laws."); *Diaz v. Paragon Motors of Woodside, Inc.*, 424 F. Supp. 2d 519, 540 (E.D.N.Y. 2006) (explaining that the MMWA is not a source of liability, "but allows a consumer to recover damages under existing state law"); *Abraham v. Volkswagen of Am., Inc.*, 795 F.2d 238, 249 (2d Cir.1986) (holding that state law governs whether lack of privity is a defense to an MMWA claim); *Sitt v. Nature's Bounty, Inc.*, 2016 U.S. Dist. LEXIS 131564 (2016 WL 5372794), at *55-56 (E.D.N.Y. Sep. 26, 2016).

conditions are met, CAFA provides an alternative basis for jurisdiction without regard for the MMWA." *Weisblum v. Prophase Labs, Inc.*, 88 F. Supp. 3d 283, 293 (S.D.N.Y. 2015) (collecting cases).

VII. Plaintiff has standing to pursue an injunction.

To establish standing to seek an injunction, a plaintiff must allege "a sufficient likelihood that [she] will again be wronged in a similar way." *City of Los Angeles v. Lyons*, 461 U.S. 95, 111 (1983). Ms. Clay alleges that she would purchase DayQuil products again if they were actually non-drowsy, but that she "faces an imminent threat of harm because she will not be able to rely on the labels in the future, and thus will not be able to purchase the products." Complaint ¶29. This is sufficient to establish standing. *Davidson v. Kimberly-Clark Corp.*, 873 F.3d 1103, 1115 (9th Cir. 2017) ("We hold that a previously deceived consumer may have standing to seek an injunction against false advertising or labeling, even though the consumer now knows or suspects that the advertising was false at the time of the original purchase…").

Defendant asserts that "the Second Circuit . . . rejected [Plaintiff's] desire [to re-purchase the product] as sufficient to confer standing to seek injunctive relief." Mot. 25 (citing *Berni v. Barilla S.P.A.*, 964 F.3d 141 (2d Cir. 2020)). But *Berni* addressed a motion for class certification, so the question was whether "injunctive relief is . . . proper for *every class member*." *Berni* at 148 (emphasis added). The court could not infer that every class member faced an imminent risk of harm because, while some purchasers may wish to re-purchase the product, others may not. *Id.*

Here, in contrast, Ms. Clay alleges that she wishes to re-purchase the DayQuil products, and therefore faces an imminent threat of harm. Thus, she has Article III standing to pursue an injunction claim. And so long as the named plaintiff can establish her own Article III standing, the Court must "defer[] consideration of the class standing question to the class certification stage." *Petrosino v. Stearn's Prods.*, 2018 U.S. Dist. LEXIS 55818, at *16 (S.D.N.Y. Mar. 30, 2018).

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Respectfully submitted,

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